National Committee on Vital and Health Statistics
Advising the HHS Secretary on National Health Information Policy

Standard Subcommittee Report Out
April 11, 2024

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Topics for Discussion

I. Communication Received Re: NCVHS recommendation on X12 Version 8020

II. ONC & SDO November Session Report Out

III. Areas of Consideration for NCVHS, for informational purposes, further review or other action

Communication Received

Re: NCVHS recommendation on X12 Version 8020, since last FC meeting

Date	Sender	Topic
11/29/23	Diana Fuller, State of Michigan Medicaid	Supports the health care industry moving to X12 Version 8020 for all currently mandated HIPAA transactions.
1/13/24	Jane Pleasants, Exec Director, SMI®, a non-profit, community of healthcare supply chain organizations	Reconsider decision regarding adoption of the updated X12 standard, specifically with regards to inclusion of the UDI-DI in claims transactions.

ONC/SDO November Session Report Out

Enhance the Committee's understanding of approaches used by Standards Development Organizations (SDOs) and certification bodies to **evaluate and assess the readiness of new and updated standards prior to release for national implementation or certification**.

Does ONC or the SDO assesses and report on backward, cross compatibility or specific anticipated issues with version update?

ONC	HL7	NCPDP	X12
Examines forward compatibility in some cases but look at the directionality of the compatibility based on how the standards are referenced.	Checks for backwards and cross-compatibility.	Checks for backwards and cross-compatibility.	Checks for backwards and cross-compatibility for individual standards.

How does ONC or the SDO assess and report on backward compatibility or specific anticipated issues with version updates?

ONC	HL7	NCPDP	X12
ONC considers the compatibility of standards relative to whether there are “breaking” changes that would affect the industry efforts to update infrastructure and standard performance, as it relates to its HIT Certification standard selection.	Documents related to the topic of backward compatibility Have summary of changes that have been made to each version of a std. Maturity-level framework applied to each artifact in the specification.	Members provided easy to understand/read documents that include Crosswalks - side-by-side Comparison of Transaction/Message Types & Transaction Guidance Crosswalk.	A list of changes is supported in the implementation guides as a reference.

How does ONC or the SDO assess whether current systems can support the functionality and the impact?

ONC	HL7	NCPDP	X12
ONC Certification for EHRs (voluntary). Testing completed prior to roll out in “real world settings.”	Testing completed prior to release. Four stages of standards development up through normative.	Does not require a specific level of testing for all new or revised standards. Rely on members, stakeholders, and Implementers through data request and harmonization efforts.	Does not require a specific level of testing for all new or revised standards. PoC initiated.

Does ONC or the SDO assess cost and value of changes within a new, updated standard?

ONC	HL7	NCPDP	X12
Benefits not yet obtained through peer reviewed national study. Look at cost (need to purchase license or otherwise obtain some type of membership to access the standards) and other factors.	No peer-to-peer validated study is available for Cost Benefit Analysis due to resource limitations and the global source of deployments. Compiles implementer case studies, includes a few of the 500 or so academic studies on FHIR.	No peer-to-peer validated study is available for Cost Benefit Analysis. Collects cost/harm data from not moving forward.	No peer-to-peer validated study available for Cost Benefit Analysis.

2024 Interoperability Standards Advisory

Referral Certification and Authorization Request and Response for Dental, Professional and Institutional Services

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	ASC X12®N/005010X217 Health Care Services Review—Request for Review and Response (278), May 2006 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●○○○○	Yes	$	Yes
Implementation Specification	HL7® FHIR® Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide	Balloted Draft	Production	●●○○○	No	Free	Yes
Implementation Specification	HL7® FHIR® Da Vinci Documentation Templates and Payer Rules (DTR) Implementation Guide	Balloted Draft	Production	●●○○○	No	Free	Yes
Implementation Specification	HL7® FHIR® Da Vinci Prior Authorization Support (PAS) Implementation Guide	Balloted Draft	Pilot	●●○○○	No	Free	Yes
Implementation Specification	HL7 CDA® R2 Implementation Guide: Dental Data Exchange	Balloted Draft	Production	●○○○○	No	Free	Yes
Implementation Specification	HL7 FHIR DaVinci Clinical Data Exchange (CDex) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	No

Health Care Attachments to Support Claims, Referrals and Authorizations

Type	Standard / Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally required	Cost	Test Tool Availability
Implementation Specification	ASC X12®N/006020X315 Health Care Services Request for Review and Response (278), September 2014 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●○○○○	No	$	No
Implementation Specification	ASC X12N/006020X313 Health Care Claim Request for Additional Information (277), September 2014 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●○○○○	No	$	No
Implementation Specification	ASC X12N/006020X316 Additional Information to Support a Health Care Services Review (275), September 2014 as an ASC X12 Standards for Electronic Data Interchange Technical Report Type 3	Final	Production	●○○○○	No	$	No
Implementation Specification	HL7 CDA® R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 1 - US Realm	Final	Production	●○○○○	No	Free	No
Implementation Specification	HL7 CDA R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1	Final	Production	●○○○○	No	Free	No
Implementation Specification	HL7 FHIR DaVinci Clinical Data Exchange (CDex) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	

HL7 Cambia Grove Innovator Fellowship

- Created value metrics framework that helps characterize various benefits of a specification, which has sufficiency, security, financial savings.
- Identified metrics of how different stakeholders might realize value. An early application of this framework appears in the Da Vinci FHIR Prior Authorization Support Specification. Considering how to apply it more widely.

NCVHS Standard Listening Session - Presentation Cambia June-9-2022

Does ONC or the SDO assess potential risks and impacts across existing standards? Status of plans for the future of ICD-11 implementation?

ONC	HL7	NCPDP	X12
Defer to CMS/National Standards Group.	Accommodates ICD-11, has collaborative agreement with WHO to develop guidance. Works directly with code set developers to ensure use in standards.	Focused on NDC code review and monitoring of status of proposed rule from FDA. ICD-11 – Updates to standards –Education Needed.	ICD-11 – Updates to standards – Education Needed & Confirmation there is no US Clinical Modification.

Does ONC or the SDO perform reporting/testing prior to proposing new and/or updated standards for national implementation or certification?

ONC	HL7	NCPDP	X12
Real world testing as new certification rules are published.	• Specification testing before and after publication • Testing events • Software to validate specifications and data • Available tools - permissive, open-source licenses. • Coordinate with ONC as they develop related tools like Inferno and a C-CDA Scorecard. • Public web interface to the validation tool set for FHIR, CDA and functional models (validator.fhir.org). • Specifications developed with corresponding reference implementation software (more practical to implement and useful learning tool).	Does not require a specific level of testing.	Does not require a specific level of testing.

Areas of Consideration for NCVHS from Panelists

- When considering different types of standards, examine the industry availability of testing infrastructure.
  - HL7 is the only SDO that presented that has a testing infrastructure.
  - Are there vendor test tools available in addition to ASETT for HIPAA Standards (X12)?
  - Funding available?
- Consider cost of obtaining standard (need to purchase license or otherwise obtain some type of membership to access the standards) and other factors.
  - Open-Source for Federally Mandated Standards?
- Consider the cost of not moving forward or promulgating a Final Rule in a timely manner. The cost of missed opportunities and use of non-standard proprietary solutions should be considered.
  - This information can be provided with proposals.

Areas of Consideration for NCVHS from Panelist

- There are differences as to what backward compatibility means and it needs to be defined. Cross compatibility was raised as a better term to test across different standards with different versions.
  - Is there or does there need to be definitions and specific documents to show backward and cross-compatibility when proposed as a national standard, in addition to cross walks?
  - How to vet and test mixed versions of standards - mixed version compatibility.
- Benefit/Cost Analysis - SDO's need to know what information is required in detail, then the SDOs will have a better chance of collecting information. SDO's do not have the hammer to collect information, unlike HHS.
  - **2022 NCVHS Recommendation** - HHS develop and publish a guidance framework for Standards Development Organizations and other industry stakeholders that outlines how to develop and report measures for new and revised standards readiness, costs, and overall adoption value to support HIPAA standards development, testing, evaluation and adoption. Provide specific governance and foundation.

Additional Comments/Questions

Supporting Documentation

HL7 – Compatibility of Data Instances

- **Forward compatibility** (content that is conformant to an old release, remaining conformant with future versions of a standard) is achieved by limiting what kinds of changes are allowed in subsequent versions.
- **Backwards compatibility** (instances created against a newer version of the specification will interoperate with older versions) is achieved by:
  - For standards like FHIR, providing advice to implementers on how they can maximize their software backwards compatibility.
  - For normative standards there are now strict rules in place about what can and cannot change in future versions, providing assurances to implementers.
  - For standards in trial use future versions may introduce breaking changes.
- The FHIR standard introduced a novel, maturity-level framework, called FMM, applied to each artifact in the specification. FMM allows implementers to judge how advanced and therefore how stable an artifact is. Maturity level is strongly related to stability. Higher maturity requires more controls to restrict breaking changes. Assigning this maturity level is influenced by the degree of testing and implementation.

X12 Backward Capability

An approach that says a trading partner who is effectively using Version X of a standard can just keep doing what they are doing and make no changes if Version Y comes in. This means that their computer-based systems would just ignore anything that changed in the new version and incur no issues in their systems moving forward.

To support emerging needs, standards need to be able to expand the links of data items to add repetitions to data that previously had a lower repetition limit and to add requirements for data that did not exist a year ago or six months ago.

Another backwards compatibility approach is when a SDO documents the enhancements that rely on trading partners, to either change their established application systems and their other computer-based solutions or to transform the exchanged information somewhere in the exchange process.

- Example, the current standard has a data element that transmits to the receiver the number of ounces that is sent, and the new version says the sender can send ounces or pounds. The trading partners either agree to: 1) continue only using ounces, 2) change the systems of both trading partners so that they both could take ounces or pounds and exchange between getting the transaction in the door and their internal systems, and, 3) allow the sender to use both units of measure and have the receiver change their internal systems to convert the information from pounds to ounces on its way in their door.

X12 Cross Compatibility

Cross compatibility is:

- separate transactions in different versions that can interact smoothly and effectively or
- separate transactions in different standards syntaxes can interact smoothly and effectively.

Cross compatibility not only requires the same data, but in many cases, the same business rules to ensure the same expectations on both sides of an exchange and calls are not increased between trading partners.